HERDING CATS: CORRALLING THE SUBJECTIVITY IN HTA

Integration of a simple framework for translating evidence into policy at a hospital-based health technology assessment unit

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Disclosure

• I have no actual or potential conflict of interest in relation to this topic or presentation.
Overview

• Conception of a simple framework to aid in the developing of recommendations

• How do we deal with the subjectivity inherent in HTA decision-making?
  • ignore it
  • informally incorporate it into the decision-making process by consulting relevant stakeholders
  • explicitly incorporate it into the decision-making process by recording value judgements of different stakeholders
  • convert value judgements of stakeholders into an objective scoring system
TAU composition and process

- **Research Staff**
  (Epidemiologist, Health economist)

- **Policy Committee**
  (physicians, nurses, allied health professionals, administration, and patients)

**Decision-making process**

- **Approved**
- **Approved for Evaluation**
- **Not approved**

**Evaluation of evidence**

**Recommendation**
HTA process

RCTs
Observational studies
Evidence
Local data

Decision-Making Process

Recommendation

Background
Pilot exercise

- Are just 3 factors (efficacy, cost, safety) sufficient to inform the final decision?
- Reviewed 24 past TAU reports
- Correlated the overall strength of 3 factors (efficacy, cost, safety) with the final recommendation

<table>
<thead>
<tr>
<th>Technology</th>
<th>Recommendation</th>
<th>Efficacy</th>
<th>Safety</th>
<th>Cost</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSD ETT tubes</td>
<td>Approved</td>
<td>Strong</td>
<td>Strong</td>
<td>Strong</td>
<td>Strong</td>
</tr>
<tr>
<td>AVB</td>
<td>Not Approved</td>
<td>Weak</td>
<td>Moderate</td>
<td>Weak</td>
<td>Weak</td>
</tr>
</tbody>
</table>

![Bar chart showing recommendation types and frequency](chart.png)
## Factors important to decision-making

### GRADE\(^1\)

<table>
<thead>
<tr>
<th>Domain</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance between desirable and undesirable effects</td>
<td>The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted</td>
</tr>
<tr>
<td>Quality of evidence</td>
<td>The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted</td>
</tr>
<tr>
<td>Values and preferences</td>
<td>The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted</td>
</tr>
<tr>
<td>Costs (resource allocation)</td>
<td>The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted</td>
</tr>
</tbody>
</table>

### OHTAC\(^2\)

<table>
<thead>
<tr>
<th>Domain</th>
<th>Sub-domain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall clinical benefit</td>
<td>Effectiveness</td>
</tr>
<tr>
<td></td>
<td>Safety</td>
</tr>
<tr>
<td></td>
<td>Burden of illness</td>
</tr>
<tr>
<td></td>
<td>Need</td>
</tr>
<tr>
<td>Feasibility of adoption</td>
<td>Economic feasibility</td>
</tr>
<tr>
<td></td>
<td>Organizational feasibility</td>
</tr>
<tr>
<td>Value for money</td>
<td>Economic evaluations</td>
</tr>
<tr>
<td>Consistency with expected societal and ethical values</td>
<td>Expected societal values</td>
</tr>
<tr>
<td></td>
<td>Expected ethical values</td>
</tr>
</tbody>
</table>

\(^1\) Grading of Recommendations Assessment, Development and Evaluation, McMaster University  
\(^2\) Ontario Health Technology Appraisal Committee
Creating a decision-making framework

To create a decision-aid tool that is:

• easy to use
• specific to a hospital setting
• captures the subjectivity inherent in HTA
Objectives

1. **Identify relevant criteria** that stakeholders in the decision-making process recognize as important to shape a recommendation;
2. Determine the extent to which the expert community agrees on the **importance** of the identified criteria;
3. Incorporate the identified domains into a **decision-aid tool**;
4. **Pilot test** the tool among TAU Policy Committee members
Objective 1: Identifying relevant criteria

- **OHTAC**
  - Clinical benefit
  - Cost
  - Feasibility
  - Ethics

- **Review of past TAU reports**
  - Two TAU members independently reviewed a random sample of past reports
  - to identify criteria that played a role in the decision-making process

- **Literature search**
  - special consideration to a survey of hospitals in France, based on an extensive literature review that included 47 decision-criteria grouped under 8 domains
Initial list of decision criteria

**Clinical Benefit**
- Magnitude of effectiveness
- Quality of evidence for effectiveness
- Safety
- Burden of illness to patient
- Absence of alternative treatment options

**Value for money**
- Costs related to the technology
- Increased hospital efficiency
- External financial support

**Feasibility**
- Ease of implementation
- Prior hospital experience with the technology
- Need for evidence of effectiveness in the local setting

**Ethics and Values**
- Disease is a public health priority
- Disease is rare
- Benefit of technology to society
- Impact on delivery of equitable care
- Impact on patient-important outcomes

**Strategic concerns**
- Impact of technology on attracting new patients and/or health professionals
- Impact on creating research opportunities and external collaborations
- Ability to offer a cutting-edge technology or new alternative treatment
- Availability of the technology in other local centres
Objective 2: Determining the importance of relevant domains

- Surveyed 61 panelists
- 52 completed responses (85%)

**Respondent representation**

<table>
<thead>
<tr>
<th>Role</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>MUHC member</td>
<td>73</td>
</tr>
<tr>
<td>HTA member</td>
<td>31</td>
</tr>
<tr>
<td>Administrator</td>
<td>23</td>
</tr>
<tr>
<td>Patient perspective</td>
<td>8</td>
</tr>
</tbody>
</table>

**McGill**

**CLINICAL BENEFIT**
The overall clinical benefit of the technology, taking into account its effectiveness, safety, and the need for the technology.
Reorganization of domains

Old version

Clinical Benefit
- Magnitude of effectiveness
- Quality of evidence for effectiveness
- Safety
- Burden of illness to patient
- Absence of alternative treatment options

Value for money
- Costs related to the technology
- Increased hospital efficiency
- External financial support

Feasibility
- Ease of implementation
- Prior hospital experience with the technology
- Need for evidence of effectiveness in the local setting

Ethics and Values
- Disease is a public health priority
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Strategic concerns
- Impact of technology on attracting new patients and/or health professionals
- Impact on creating research opportunities and external collaborations
- Ability to offer a cutting-edge technology or new alternative treatment
- Availability of the technology in other local centres

New version

Clinical Benefit
- Magnitude of effectiveness
- Quality of evidence for effectiveness
- Safety

Value for money
- Budget impact (Net cost)
- Costs avoided/increased hospital efficiency
- Budget impact on other departments
- Cost-effectiveness

Feasibility
- Availability of local expertise
- Disruptiveness
- Need to generate local evidence
- Impact on cross-institution collaboration
- Personnel satisfaction
- Impact of innovativeness of the technology

Impact on patient
- Impact on patient convenience
- Personal utility: patient values and preference
- Patient-reported outcomes (QoL)

Impact on health system
- Benefit to society (reduces health care costs)
- Burden on other health care centres
- Need: unnecessary duplication

Strategic concerns
- Stakeholder pressure
- No. of patients affected by technology
- Availability of external funding

Ethical considerations
Objective 3. Creating the framework

1. After HTA completed
   - By TAU research staff
   - Rate favourability of each domain

2. Before committee meeting
   - By Policy committee members
   - Rate importance of each domain

3. At committee meeting
   - By Policy committee members
   - Deliberate results from tool and make recommendation
Pilot testing the tool

To evaluate the use of a hydrogel spacer as part of the external beam radiation therapy protocol in patients with localized prostate cancer at the MUHC

Policy Question

Population

Intervention

Comparator

Outcome

Patients with localized prostate cancer receiving radiotherapy

External beam radiotherapy (EBRT) + spacer gel

EBRT alone

Acute and late QoL (using EPIC), and adverse events (using RTOG or CTCAE)
Creating the framework

1. TAU researchers complete the HTA and record their findings for each criterion.
2. They also rate whether the findings are favourable:
   - Yes
   - No
   - Maybe
   - Need more information

GOAL: To ensure a systematic approach to considering different factors relevant to the decision-making process.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Findings of the Health Technology Assessment Report</th>
<th>Do these findings favour the approval of VA-ECMO for cardiac arrest at the MUHC? [Completed by TAU]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of the evidence</td>
<td>The quality of the evidence is low. A number of propensity score adjusted studies have been published, but these have several limitations.</td>
<td>No</td>
</tr>
<tr>
<td>Safety of the technology</td>
<td>No comparative studies. A meta-analysis of case series found a high rate of complications with VA-ECMO.</td>
<td>No</td>
</tr>
</tbody>
</table>
Creating the framework

- Each committee member sent a link to the decision-aid tool to be completed online, along with the technology assessment report.
- Policy committee members rate the importance of each criterion based on their values and preferences and within the context of the technology.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Findings of the Health Technology Assessment Report</th>
<th>Do these findings favour the approval of VA-ECMO for cardiac arrest at the MUHC? [Completed by TAU]</th>
<th>How important is this criterion in shaping the final recommendation? [Completed by each committee member]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of the evidence</td>
<td>The quality of the evidence is low. A number of propensity score adjusted studies have been published, but these have several limitations.</td>
<td>No</td>
<td>Very Important</td>
</tr>
<tr>
<td>Safety of the technology</td>
<td>No comparative studies. A meta-analysis of case series found a high rate of complications with VA-ECMO.</td>
<td>No</td>
<td>Very important</td>
</tr>
</tbody>
</table>
Illustration

• SurveyGizmo

• https://s-6ff987-i.sgizmo.com/s3/i-19Jk34lBN7VJczNork-3120373/?sguid=19Jk34lBN7VJczNork
Creating the framework

GOAL:

• To provide a visual means for arriving at a final recommendation,
• by juxtaposing the importance rating for each domain against the results of the health technology assessment.
• For a technology to be approved, a majority of criteria considered important should also have received favourable findings.
• Encourages participation free of group pressure as recommendation made anonymously through our online tool ahead of the committee meeting.
Creating the framework

- At the meeting, the distribution of importance ratings and recommendations across the committee will be presented (see illustration).
- Committee members will have the opportunity to express their views and justify extenuating reasons, until a consensus on the final recommendation is reached.
- All reasons will be explicitly documented.

**Goal:** To create a structured and transparent decision-making process.

**Distribution of Recommendation Types Among Committee Members**

- Approved: 69%
- Approved for Evaluation: 23%
- Not Approved: 8%
## Results of pilot test

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not completed</td>
<td>5</td>
<td>31.3</td>
</tr>
<tr>
<td>Complete</td>
<td>11</td>
<td>68.7</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>100</td>
</tr>
</tbody>
</table>

- **Objective 4**
  - Approved for Evaluation: 18%
  - Not Approved: 82%
## Distribution of Importance ratings

<table>
<thead>
<tr>
<th>DOMAINS</th>
<th>CRITERIA</th>
<th>FAVOURS APPROVAL?</th>
<th>% CONSIDERING CRITERION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Very Important</td>
<td>Somewhat</td>
</tr>
<tr>
<td>Clinical benefit</td>
<td>Magnitude of effectiveness</td>
<td>No</td>
<td>73</td>
</tr>
<tr>
<td></td>
<td>Quality of the evidence</td>
<td>No</td>
<td>55</td>
</tr>
<tr>
<td></td>
<td>Safety of the technology</td>
<td>Maybe</td>
<td>55</td>
</tr>
<tr>
<td>Impact on Patient</td>
<td>Patient preference</td>
<td>No data</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>Impact on patient convenience</td>
<td>Maybe</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>Patient-reported outcomes</td>
<td>No</td>
<td>82</td>
</tr>
<tr>
<td>Value for money</td>
<td>Net cost</td>
<td>No</td>
<td>46</td>
</tr>
<tr>
<td></td>
<td>Costs avoided (increased hospital efficiency)</td>
<td>Maybe</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>Impact on budget of other departments</td>
<td>Maybe</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>Cost-effectiveness</td>
<td>No</td>
<td>64</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Availability of local expertise</td>
<td>Yes</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>Disruptiveness</td>
<td>Yes</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>Need to generate local evidence</td>
<td>Maybe</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>Impact on cross-institution collaboration</td>
<td>No data</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Satisfaction of personnel</td>
<td>No data</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Impact of innovativeness of the technology</td>
<td>No</td>
<td>27</td>
</tr>
<tr>
<td>Impact on healthcare system /society</td>
<td>Benefit of the technology to society</td>
<td>No</td>
<td>55</td>
</tr>
<tr>
<td></td>
<td>Burden on other healthcare centres/services</td>
<td>Maybe</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>Need for the technology</td>
<td>Maybe</td>
<td>45</td>
</tr>
<tr>
<td>Ethical considerations</td>
<td>Ethical considerations</td>
<td>Yes</td>
<td>46</td>
</tr>
<tr>
<td>Strategic considerations</td>
<td>Stakeholder pressure</td>
<td>No</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Availability of external funding</td>
<td>No</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>Number of patients affected by technology</td>
<td>Maybe</td>
<td>18</td>
</tr>
</tbody>
</table>
Feedback: Strengths

- compels members to **consider all the various criteria** that go into shaping the final recommendation
- promotes **transparency** and **accountability**
- particularly useful in evaluating less straightforward technologies by allowing stakeholders to **address the underlying nuances in a methodical** fashion
- the juxtaposition of the evidence against the importance rating obliges stakeholders to acknowledge the lack of evidence for domains they consider important, thus **tempering their championing of an unproven technology.**
- **encourages increased participation** from all members by soliciting their input in an anonymous fashion before the meeting, free of group pressure and the impact of influential members.
Feedback: Suggestions

- Blinding committee members to judgements of HTA authors
- Allowing committee members to make their own judgments re: evidence; or make changes to HTA author judgments
How do we deal with the subjectivity inherent in HTA decision-making?

- ignore it
- informally incorporate it into the decision-making process by consulting relevant stakeholders
- explicitly incorporate it into the decision-making process by recording value judgements of different stakeholders
- convert value judgements of stakeholders into an objective scoring system

Why not quantitative methods like MCDA (Multi-criteria Decision Analysis)?
- a scoring system obscures the subjectivity implicit in the assignment of weights
Conclusion

• The decision-making process is inherently subjective
• dependent on value judgements
• But this should not be perceived as threats to scientific objectivity
Thank you!

• This work will be published in a forthcoming issue of IJTAHC

• For further information on TAU or our reports: https://www.muhc.ca/tau/
### Review table

24. The following are criteria you rated as *Very Important*, and their corresponding TAU findings:

<table>
<thead>
<tr>
<th>Criteria</th>
<th>TAU finding favours approval?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effectiveness</td>
<td>Yes</td>
</tr>
<tr>
<td>Safety</td>
<td>Maybe</td>
</tr>
<tr>
<td>Patient-reported outcomes</td>
<td>Yes</td>
</tr>
<tr>
<td>Cost-effectiveness</td>
<td>Maybe</td>
</tr>
<tr>
<td>Availability of local expertise</td>
<td>No</td>
</tr>
<tr>
<td>Disruptiveness</td>
<td>Yes</td>
</tr>
<tr>
<td>Benefit to society</td>
<td>Yes</td>
</tr>
<tr>
<td>Burden on other healthcare services</td>
<td>No</td>
</tr>
<tr>
<td>Need for the technology</td>
<td>Maybe</td>
</tr>
<tr>
<td>Ethical considerations</td>
<td>Yes</td>
</tr>
<tr>
<td>Availability of external funding</td>
<td>Yes</td>
</tr>
</tbody>
</table>